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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Naoya Tsurushita, *et al.*

Application No.: 10/788,625

Filed: February 26, 2004

For: **HUMANIZED CHICKEN
ANTIBODIES**

Art Unit: 1644

Examiner: Not Yet Assigned

Confirmation No. 6526

Atty. Docket: 05882.0044.NPUS02

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- 1. This Information Disclosure Statement is being filed;
 - ☐ a. Within three months of the U.S. filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ b. Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - c. Before the mailing date of a first Office Action on the merits;
 - ☐ d. Before the mailing of a first Office Action after filing of a request for continued examination under § 1.115.

No statement under 37 C.F.R. § 1.97(e) or fee is required.

or;

- ☐ 2. This Information Disclosure Statement is being filed after the period specified in paragraph 1(a)-1(d) above, but before the mailing date of a Final Rejection or Notice of Allowance, or action that otherwise closes prosecution in the application, and
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable

inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2), or

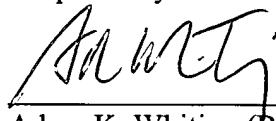
- ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but on or before payment of the Issue Fee. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i), and
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1), or
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.

- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination.
- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing docket number 05882.0044.NPUS02.

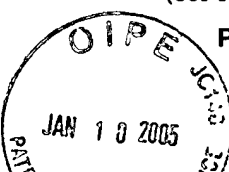
Respectfully submitted,



Adam K. Whiting (Reg. No. 44,400)

Date: January 10, 2005

HOWREY SIMON ARNOLD & WHITE, LLP
301 Ravenswood Avenue
Box No. 34
Menlo Park, CA 94025
(650) 463-8133

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)  PTO FORM 1449	ATTY. DOCKET NO. 05882.0044.NPUS02	APPLICATION NO. 10/788,625
	APPLICANT Naoya Tsurushita, et al.	
	FILING DATE February 26, 2004	GROUP 1644

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1.	5,530,101	06/25/96	Queen, et al.			
	A2.	5,585,089	12/17/96	Queen, et al.			
	A3.	5,648,467	07/15/97	Trinchieri, et al.			
	A4.	5,780,597	07/14/98	Gately, et al.			
	A5.	5,811,523	09/22/98	Trinchieri, et al.			
	A6.	6,180,370	01/30/01	Queen, et al.			
	A7.	6,300,478	10/09/01	Trinchieri, et al.			
	A8.	6,410,824	06/25/02	Ehrhardt, et al.			
FOREIGN PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)							
	C1.	Asaoka, H. et al., "Two chicken monoclonal antibodies specific for heterophil Hanganutziu-Deicher antigens," <i>Immunol. Lett.</i> 32:91-6 (1992)					
	C2.	Borsig, et al., "Synergistic effects of L- and P-selectin in facilitating tumor metastasis can involve non-mucin ligands and implicate leukocytes as enhancers of metastasis," <i>Proc. Natl. Acad. Sci.</i> , 99(4):2193-8 (2002)					
	C3.	Carroll, S. B. et al., "Antibodies to Calf Thymus RNA Polymerase II from Egg Yolks of Immunized Hens," <i>J. Biol. Chem.</i> 258:24-26 (1983)					
	C4.	Co, et al., "Humanized antibodies for therapy," <i>Nature</i> 351: 501-2 (1991)					
	C5.	Gassmann, M. et al., "Efficient production of chicken egg yolk antibodies against a conserved mammalian protein," <i>J. FASEB</i> 4(8): 2528-32 (1990)					

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

LIST OF REFERENCES CITED BY APPLICANT <i>(Use several sheets if necessary)</i> PTO FORM 1449	ATTY. DOCKET NO. 05882.0044.NPUS02	APPLICATION NO. 10/788,625
	APPLICANT Naoya Tsurushita, et al.	
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C6.	Jones, <i>et al.</i> , "Replacing the complementarity-determining regions in a human antibody with those from a mouse," <i>Nature</i> 321: 522-25 (1986)
C7.	Katz, D. <i>et al.</i> , "Use of Chicken and Rabbit Antibodies in a Solid Phase Protein a Radioimmunoassay for Virus Detection," <i>J. Virol. Methods</i> 12: 59-70 (1985)
C8.	Larsson, A. <i>et al.</i> , "Chicken IgY: Utilizing the Evolutionary Difference," <i>Comp. Immunol. Microbiol. Infect. Dis.</i> 13(4):199-201 (1990)
C9.	Larsson, A. <i>et al.</i> , "Chicken antibodies: a tool to avoid false positive results by rheumatoid factor in latex fixation tests," <i>J. Immunol. Methods</i> 108:205-8 (1988).
C10.	Larsson, A. <i>et al.</i> , "Determination of circulating immune complexes by chicken anti-human C3 and anti-human C1q microELISA," <i>J. Immunol. Methods</i> 113:93-99 (1988)
C11.	Langone, J.J. <i>et al.</i> , "Radioimmunoassays for Protein A of <i>Staphylococcus aureus</i> ," <i>J. Immunol. Methods</i> 63:145-57 (1983)
C12.	Pink, J. <i>et al.</i> , "Counting Components of the Chicken's B Cell System," <i>Immunol. Rev.</i> 91:115-28 (1986)
C13.	Queen <i>et al.</i> , "A humanized antibody that binds to the interleukin 2 receptor," <i>Proc. Natl. Acad. Sci. USA</i> 86:10029-33 (1989)
C14.	Riechmann <i>et al.</i> , "Reshaping human antibodies for therapy," <i>Nature</i> 332: 323-7 (1988)
C15.	Rader, C., <i>et al.</i> "The Rabbit Antibody Repertoire as a Novel Source for the Generation of Therapeutic Human Antibodies," <i>J. Biol. Chem.</i> 275(18):13668-76 (2000)
C16.	Steinberger, P., <i>et al.</i> "Generation and Characterization of a Recombinant Human CCR5-specific Antibody," <i>J. Biol. Chem.</i> 275(46):36073-78 (2000)
C17.	Verhoeyen <i>et al.</i> , "Reshaping Human Antibodies; Grafting an Antilysozyme Activity," <i>Science</i> 239: 1534-36 (1988)

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with **MPEP 609**; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.